

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)))))	MDL NO. 1456 Civil Action No. 01-12257-PBS Subcategory Case No. 06-11337-PBS
THIS DOCUMENT RELATES TO: <i>United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation, Civil Action No. 09-CV-10547, and</i> <i>United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation, Civil Action No. 00-CV-10698</i>))))))))))))	Judge Patti J. Saris

**THE CITY OF NEW YORK AND NEW YORK COUNTIES' MEMORANDUM OF LAW IN
SUPPORT OF THEIR MOTION TO INTERVENE FOR THE LIMITED PURPOSE OF
OBJECTING TO THE VEN-A-CARE/SCHERING/WARRICK PROPOSED SETTLEMENT**

The City of New York and New York Counties (hereinafter “the NY Counties”) in MDL 1456, by and through their attorneys of record, file this memorandum of law in support of their motion to intervene for the limited purpose of objecting to the proposed Settlement Agreement and Release and Order Approving Settlement and Dismissal with Prejudice between Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation and Ven-A-Care of the Florida Keys, Inc. [Dkt. No. 6173-2] (hereinafter “Proposed Settlement and Order”). The Proposed Settlement and Order, as drafted, essentially asks this Court for an advisory opinion on a matter that is not a case nor controversy before it and seeks entry of findings that are unsupported by the record and potentially highly prejudicial to the NY Counties’ case. The

NY Counties' case against Schering/Warrick includes the same Covered Drugs and Conduct as are at issue in the Proposed Settlement and Order. *See* Comparison of Schering drugs at issue in the NY Counties case with Schering Covered Drugs included in Proposed Settlement (attached hereto as Exhibit A) and Comparison of Warrick drugs at issue in the NY Counties case with Warrick Covered Drugs included in Proposed Settlement (attached hereto as Exhibit B). Schering/Warrick's motion to dismiss the NY Counties' claims against it was denied. *See In re Pharm. Indus. Average Wholesale Litig.*, 498 F. Supp. 2d 402 (D. Mass. 2007).

BACKGROUND AND OBJECTIONS

The events leading to the Proposed Settlement and Order are fully set forth in the Corrected United States' Objection to the Proposed Settlement between Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation and Ven-A-Care of the Florida Keys, and Proposed Order, filed on July 21, 2009 [Dkt. No. 6274] ("the DOJ Objection") at 1-2 and the Commonwealth of Massachusetts' Memorandum in Support of its Motion to Intervene for the Limited Purpose of Objecting to the Ven-A-Care/Schering/Warrick Settlement Agreement, filed July 22, 2009 [Dkt. No. 6276] at 2-4, adopted herein for the sake of efficiency and to avoid duplicative filings.

The NY Counties' objections to the Proposed Settlement are for the most part substantively identical to the DOJ Objections in ¶¶4 and 5 and Massachusetts' Objection Nos. 1 and 2 of the Commonwealth of Massachusetts' Objections to the Ven-A-Care/Schering/Warrick Settlement Agreement and Order of Dismissal [Dkt. No. 6275-2], which plaintiffs also incorporate herein for the sake of efficiency and to avoid redundant filings. They are, *en breve*, that the Proposed Settlement and Order constitutes, *inter alia*, an improper request for an

advisory opinion where there is no case or controversy and includes proposed findings regarding Schering/Warrick's reported prices that are unsupported by facts before the Court.

In addition, the Proposed Settlement and Order seeks to have the Court make a finding of fact regarding Schering/Warrick's compliance with the liability standards set forth in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007) ("Track One Opinion"). *See* Proposed Order at ¶6. However, the proper approach to at least one of those standards (specifically, how to determine what percentage of sales are within 5% of WAC or "the WAC List Price Test") is unresolved (as this Court knows) given the pendency of GlaxoSmithKline's Motion for Partial Summary Judgment in the NY Counties case.¹ Until it is determined which data properly should be considered in the WAC List Price Test, it cannot be fairly or accurately stated, let alone "found" by this Court, that any NDC passes or fails this test. (As of this filing, the parties to the GSK motion await scheduling of what is likely to be the final oral argument on the GSK motion.)

Further, on the instant record the Court cannot find that Schering's AMPs are appropriate proxies for ASPs for purposes of an ASP/AWP spread test. ASP, as defined by 42 U.S.C. § 1395w-3a(c), is to be calculated as a net figure that accounts for all rebates. "[S]uch price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r-8)." *Id.* at § 1395w-3a(c)(3). AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1)(A). Until it is known whether Schering includes "all rebates"

¹ *See* briefing and supplemental briefing on GSK's Motion for Partial Summary Judgment [Dkt. Nos. 5706, 5707, 5708, 5892, 5893, 5894, 5940, 5960, 6155, and 6250].

in its AMPs (and Schering may not and such may be entirely proper for purposes of AMP reporting), it would not be appropriate for the Court to determine that Schering's AWPs pass the ASP/AWP spread test based on Schering's AMPs.

ARGUMENT

I. The NY Counties Can Intervene In These Cases Because the Parties' Proposed Settlement Will, As A Practical Matter, Impair and Impede the NY Counties' Case.

Fed. R. Civ. P. 24(a)(2) provides that, on timely motion, the court must permit anyone to intervene who:

Claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposition of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.

In order to qualify as an Intervenor as of right under Rule 24(a)(2), a movant must (1) show it has made a timely motion to intervene; (2) demonstrated a sufficient stake in the ongoing lawsuit; (3) show that resolution of the lawsuit in its absence threatens to prejudice its interests; and (4) negate the likelihood that some other party can be expected to adequately protect its interests. *See Negron-Almeda v. Santiago*, 528 F. 3d 15, 22 (1st Cir. 2008); *Geiger v. Foley Hoag LLP Retirement Plan*, 521 F. 3d 60, 64 (1st Cir. 2008); *B. Fernandez & Hnos, Inc. v. Kellogg USA, Inc.*, 440 F. 3d 541, 544-45 (1st Cir. 2006).

The NY Counties satisfy each of these criteria. First, the motion to intervene is timely because the papers submitted in support of the Proposed Settlement and Order were only recently filed and the matter has not yet been heard by this Court.

Second, the NY Counties have a stake in the issues raised by the Proposed Settlement and Order because it seeks entry of findings of fact regarding the same Schering/Warrick pricing

practices that are currently being litigated by the NY Counties. The NY Counties' case concerns the same Covered Conduct and Drugs. *See Exhibits A and B hereto.*

Third, the NY Counties' interests would be prejudiced should the Court approve the Proposed Settlement and Order as drafted because Schering/Warrick will most certainly use the findings contemplated therein against the NY Counties' claims. In addition, as set forth above, the findings now included in the Proposed Settlement and Order lack sufficient evidentiary basis and may result in inconsistent rulings from this Court. For example, the proposed findings include that the reported prices for the Covered Drugs were not "false or fraudulent statements . . . misleading, deceptive or unfair". *See Proposed Order at ¶3.* But as set forth in the DOJ Objection at ¶5, which has been incorporated herein, there is not a sufficient evidentiary record on which this finding can be made. In addition, as the Court is aware given the ongoing proceedings in respect of GSK's motion for partial summary judgment², the question of which data is to be considered for proper application of the WAC List Price Test (one of the three tests established by the Court in the Track One trial that collectively bear on whether a reported price is "false, deceptive or unfair" (*See Track One Opinion*, 491 F. Supp. 2d at 105) is not yet decided. It would be premature, factually inaccurate and potentially highly prejudicial for the Court to enter findings that Schering/Warrick NDCs pass the WAC List Price Test when it is as yet unresolved what data must or can be considered for proper application of that test.

Similarly, the parties to the Proposed Settlement do not present any evidence regarding how Schering/Warrick calculates its AMPs and what rebates or other incentives are included

² Plaintiffs' supplemental briefing in opposition to GSK's motion was filed June 16, 2009 [Dkt No. 6155]. GSK's supplemental briefing was filed on July 2, 2009 [Dkt No. 6250]. The parties await scheduling of the final oral argument on the motion.

therein. Therefore this Court cannot “find” that Schering/Warrick AMPs can serve as a proxy for an ASP in the context of an ASP/AWP spread test. ASP, as defined by 42 U.S.C. § 1395w-3a(c), is to be calculated as a net figure that accounts for all rebates. “[S]uch price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r-8).” *Id.* at § 1395w-3a(c)(3). There is no record evidence that Schering AMPs are calculated in such fashion³.

Fourth, the parties to the Proposed Settlement cannot be expected to adequately represent the NY Counties’ interests. Schering/Warrick is a defendant in the NY Counties’ case and adverse to the NY Counties’ interests. The Relator has signed the Proposed Settlement which purports to advocate the findings of fact regarding liability for drugs it did not even seek to litigate until the settlement and can hardly be expected to protect the NY Counties’ interests.

Alternatively, the Court may also grant the NY Counties permission to intervene as a matter of discretion, pursuant to Fed. R. Civ. P. 24(b)(1)(B). The Court enjoys “very broad discretion” in deciding whether to allow a movant to intervene pursuant to Rule 24(b) and “can consider almost any factor rationally relevant.” *Daggett v. Commission on Government Ethics and Election Practices*, 172 F. 3d 104, 112-13 (1st Cir. 1999); *see also Travelers Indem. Co. v. Bastianelli*, 250 F.R.D. 82, 85 (D. Mass. 2008). As discussed above, the NY Counties’ claims would clearly be impaired or impeded by the proposed settlement and the NY Counties are unable to protect their interests unless this motion is granted. Although the Court must consider whether “the intervention will unduly delay or prejudice the adjudication of the original parties’

³ The New York Counties emphasize that they are not arguing or implying that Schering/Warrick miscalculated their AMPs. The question is only whether Schering/Warrick

rights" (Fed. R. Civ. P. 24(b)(3)) there is no basis to suggest the NY Counties' intervention will cause delay or prejudice given the timing of this motion and the consistency of the NY Counties' position with the DOJ Objections already filed.⁴

CONCLUSION

For all the foregoing reasons, the NY Counties respectfully requests that their Motion to Intervene be granted for the limited purposes of objecting to the Proposed Settlement and Order as set forth herein.

Dated: July 23, 2009

Respectfully submitted,

**City of New York and New York Counties in
MDL 1456 except Nassau and Orange by**

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AMPs can serve as proxy for ASP.

⁴ In the event the Court denies the NY Counties' motion to intervene, the NY Counties respectfully request the Court to consider their arguments as if they were presented in the context of an amicus curiae brief. *See, e.g., Crosby Steam Gage & Valve Co. v. Manning, Maxwell & Moore*, 51 F. Supp. 972, 973 (D. Mass. 1934) (if intervention is inappropriate a third party can contribute most effectively by submitting an amicus curiae brief). The NY Counties can file the appropriate motion and accompanying memorandum of law if the Court so desires.

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CERTIFICATE OF SERVICE

I, Jocelyn R. Normand, hereby certify that I caused a true and correct copy of the foregoing to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: July 23, 2009

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